Pyrethroid Problem Formulation Overview

Nick Poletika

Dow AgroSciences LLC
Indianapolis, IN
on behalf of the Pyrethroid Working Group
Pyrethroid Forum
30 April 2007

Dow AgroSciences™

Pyrethroid Working Group (PWG)

- Consortium of pyrethroid registrants formed in 1990 at the behest of US EPA
  - Initial objective was to collectively address questions raised by the EPA related to aquatic toxicity
  - Since the implementation of the Food Quality Protection Act in 1996, the PWG expanded its scope to address aggregate and cumulative risk assessments and common mechanism of pyrethroids
  - Have been tracking pyrethroid related issues in CA since 1999
- Current members include
  - Bayer, DuPont, FMC, Pytech (Dow/Cheminova JV), Syngenta, and Valent

CA Pyrethroid Re-evaluation: Why the PWG?

- Member companies have interests in all “Group 3” active ingredients
  - Bifenthrin, cyfluthrin, beta-cyfluthrin, gamma-cyhalothrin, lambda-cyhalothrin, cypermethrin, zeta-cypermethrin, deltamethrin, esfenvalerate, fenpropathrin, and permethrin
  - Are responsible for required regulatory data packages
- Our pyrethroid technical (environmental and toxicology) and regulatory experts already working collectively
- Working together under the umbrella of the PWG to address the pyrethroids concerns in CA makes sense for everybody!
  - Large volume of work
  - Facilitates collaboration with other stakeholders

Outline

- Ecological risk assessment
- Why problem formulation?
- Elements of a problem formulation
- Problem formulation for pyrethroids
- Summary conceptual model
- Detailed conceptual models
- Analysis plan

What is Ecological Risk Assessment?*

- ERA is the practice of determining the nature and likelihood of effects of our actions on animals, plants, and the environment. It is a useful management tool:
  - Highlights the greatest risks, which is helpful for allocating limited resources
  - Allows decision makers to ask “what if ” questions regarding the consequences of potential management actions
  - Facilitates explicit identification of environmental values of concern
  - Identifies critical knowledge gaps, thereby helping to prioritize future research needs

* [SETAC] Society of Environmental Toxicology and Chemistry. 1997. Technical issue paper: Ecological risk assessment. Pensacola, FL, USA: SETAC. 4 p. Reference applies to slides 5-8.

What are ERA's Basic Concepts?

- Ecological risks are 1) estimated from the relationship between exposure and effects and 2) made with varying degrees of uncertainty.
- ERAs evaluate two basic elements: exposure and effects.
  - Exposure is the interaction of stressors with receptors. Measures of exposure can include concentrations of contaminants or physical changes in habitat.
  - The analysis of effects evaluates changes in the nature and magnitude of effects as exposure changes.

Integration of Exposure and Effects

- Integrating exposure and effects information leads to an estimation of risk, the likelihood that adverse effects will result from exposure.

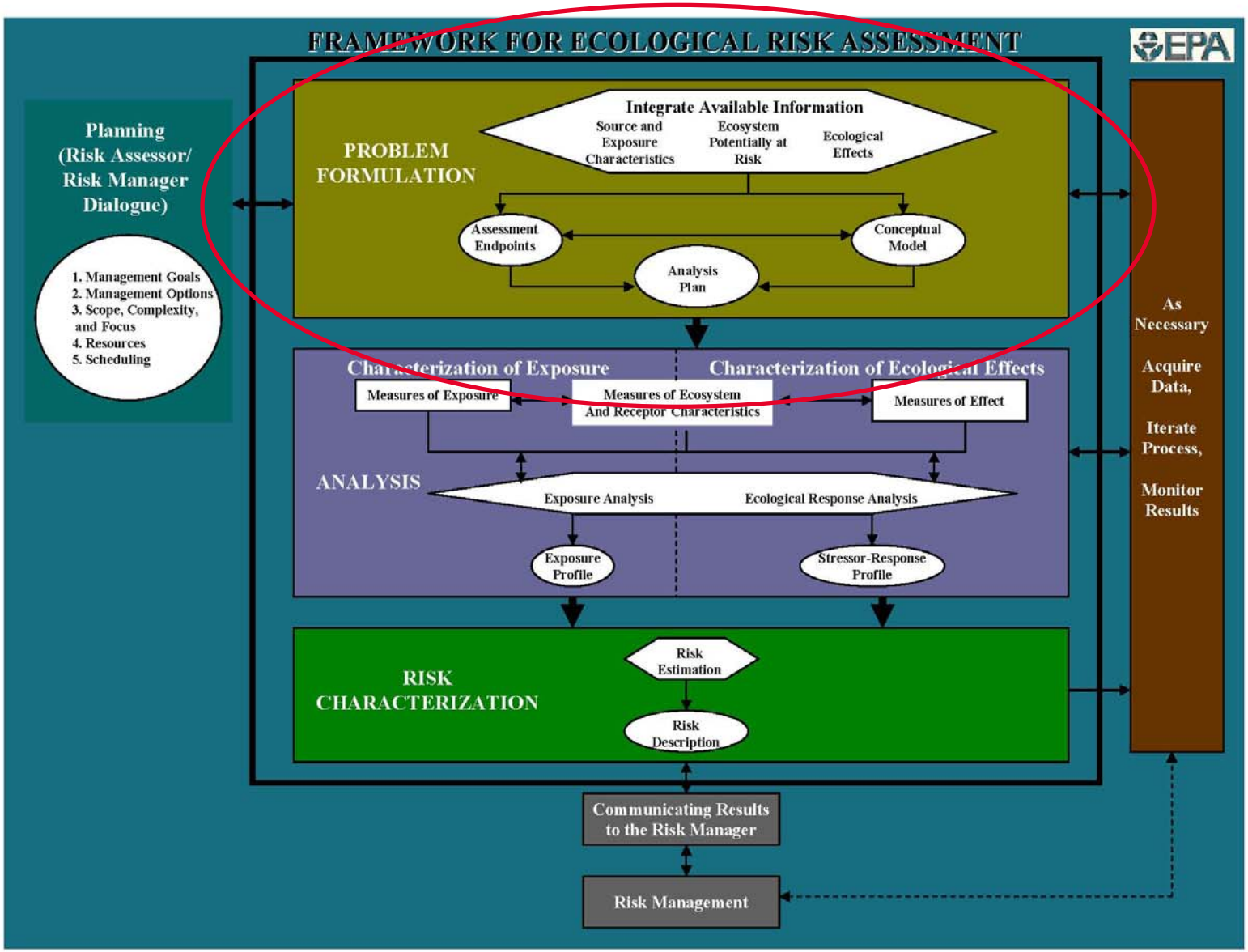
Why Problem Formulation?

- ERAs include the following:
- 1) Problem formulation: clearly defining the inquiry
  - Value: ensures the correct questions are asked
- 2) Analysis: characterizing potential or existing exposure to stressors and their effects
  - Problem formulation analysis plan specifies relevant data and appropriate methods of analysis
- 3) Risk characterization: integrating and evaluating exposure and effects information
  - If answer is certain, communicate results
  - If uncertainty exists, conduct a new problem formulation

Full Framework for Programmatic ERA*

- Planning
- Problem formulation
- Analysis
- Risk characterization
- Communicating results to risk manager
- Iterate, as necessary
- Risk management

* USEPA, 1998. Guidelines for ecological risk assessment. EPA/630/R-95/002F.Risk Assessment Forum, U.S. Environmental Protection Agency, Washington, DC. Reference applies to slides 9-11.



Elements of a Problem Formulation

- Problem formulation results in three products:
- (1) **assessment endpoints** that adequately reflect management goals and the ecosystem they represent
- (2) **conceptual models** that describe key relationships between a stressor and assessment endpoint or between several stressors and assessment endpoints
- (3) an **analysis plan**.

Problem Formulation for Pyrethroids

- Based on a problem formulation drafted by USEPA OPP for federal conditional registrations
- Follows USEPA 1998 Guidelines
- Modified to reflect new knowledge and specific California conditions

FIFRA Management Goal

- The management goal is the protection of aquatic communities from unreasonable risk or injury, taking into account the economic, social, and environmental costs and benefits from the use of synthetic pyrethroid insecticides.

Stressor

- The compounds under consideration in this comparative assessment are third and fourth generation synthetic pyrethroids.
  - Develop an understanding of the stressors of concern (Michael Dobbs' presentation)

Stressor Mode of Action

- The primary biological effects on insects and vertebrates reflect an inhibition of the correct firing of neurotransmitter to deliver signals from one cell to another.

Stressor Fate and Disposition

- Lipophilic compounds that bind to sediments
- Stable to hydrolysis (pH 5 – pH 7)
- Compounds are moderately to highly persistent and immobile
- Bioaccumulation in fish and higher vertebrate tissue is low because of rapid metabolism via hydrolysis and mixed function oxygenase.

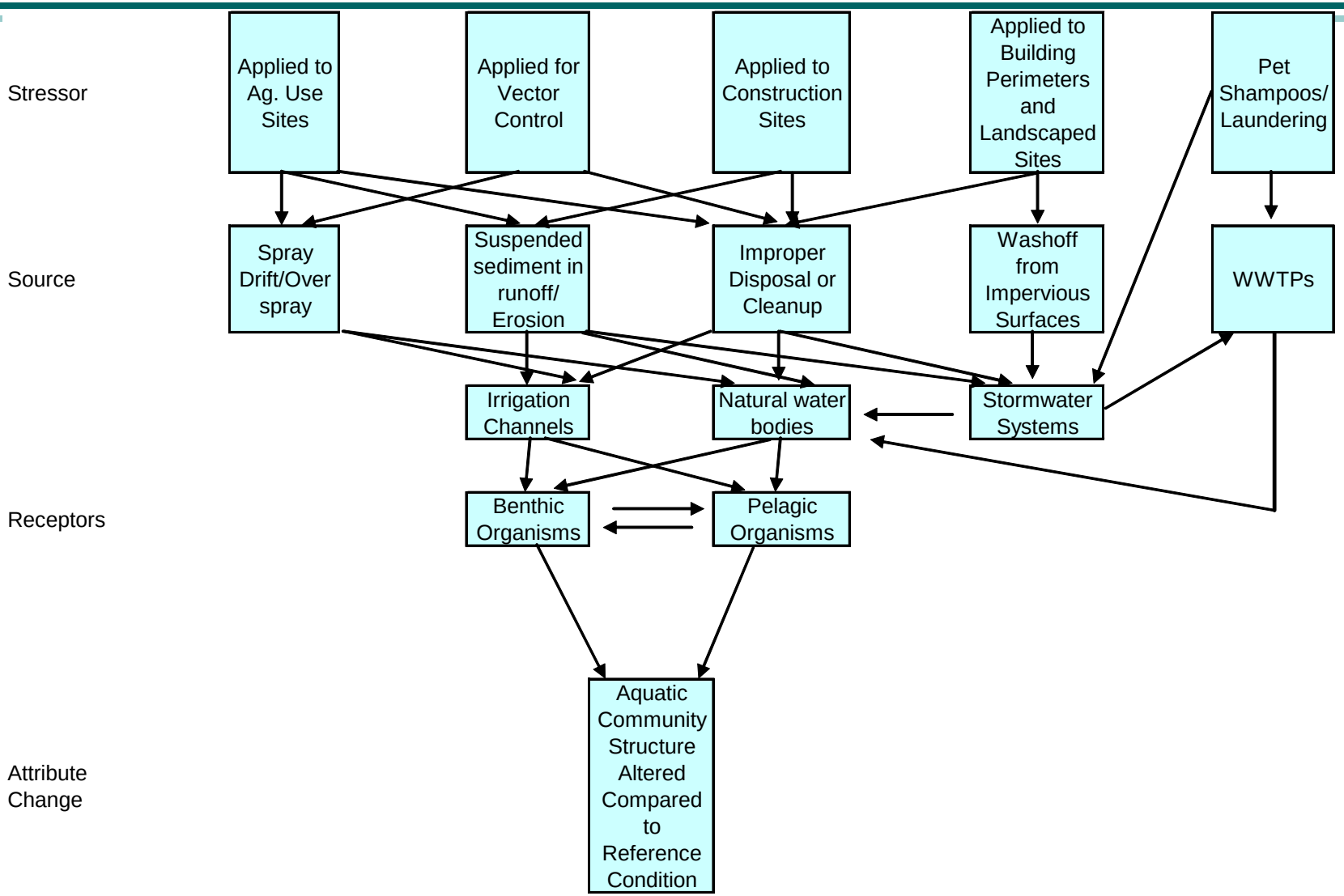
Assessment Endpoints

- Explicit statements of the characteristics of the environment (aquatic) that are to be protected
  - Community structure altered compared to reference condition as a result of
    - Direct effects to fish and aquatic invertebrates (water column) via acute toxicity
    - Direct effects to aquatic invertebrates (sediment and pore-water) via acute and/or chronic toxicity
    - Indirect effects to fish (sediment and pore-water) via food chain alteration

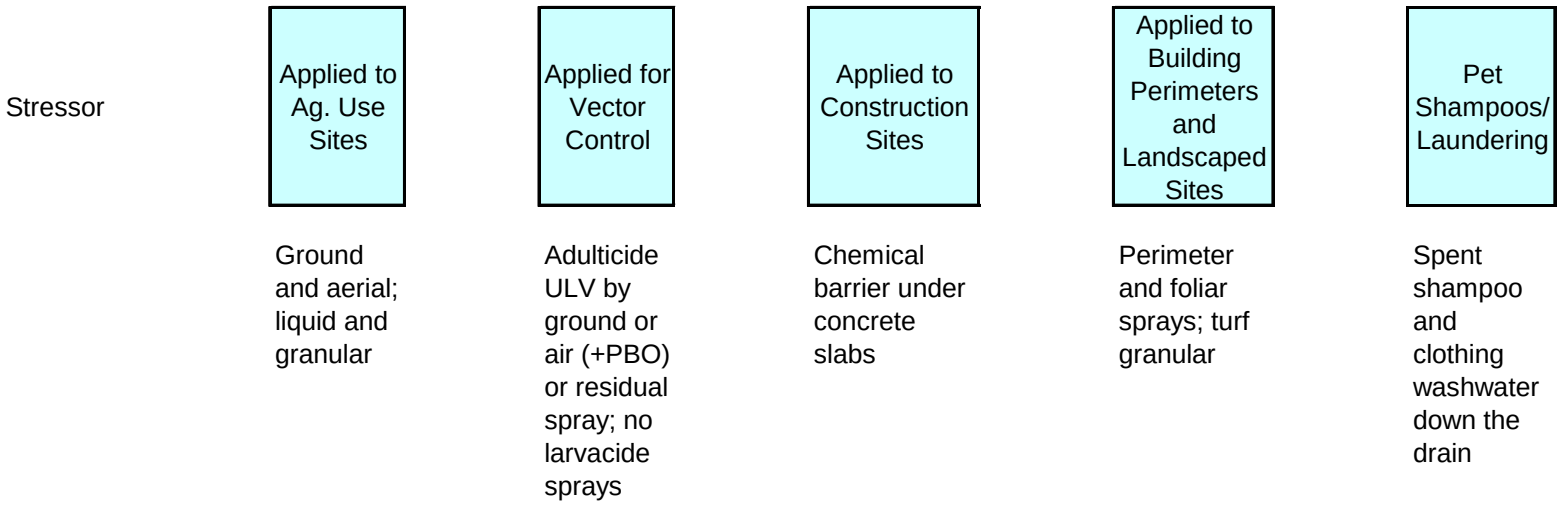
Measurement Endpoints

- The measurement endpoints are defined as the way in which assessment endpoints can be evaluated.
  - Hazard assessment from standard single chemical toxicity testing (acute and chronic endpoints) and peer reviewed literature
    - Toxicity in sediment predicted by equilibrium partitioning model
  - Incident reports (fish kills)
  - Mesocosm studies
  - Biological monitoring

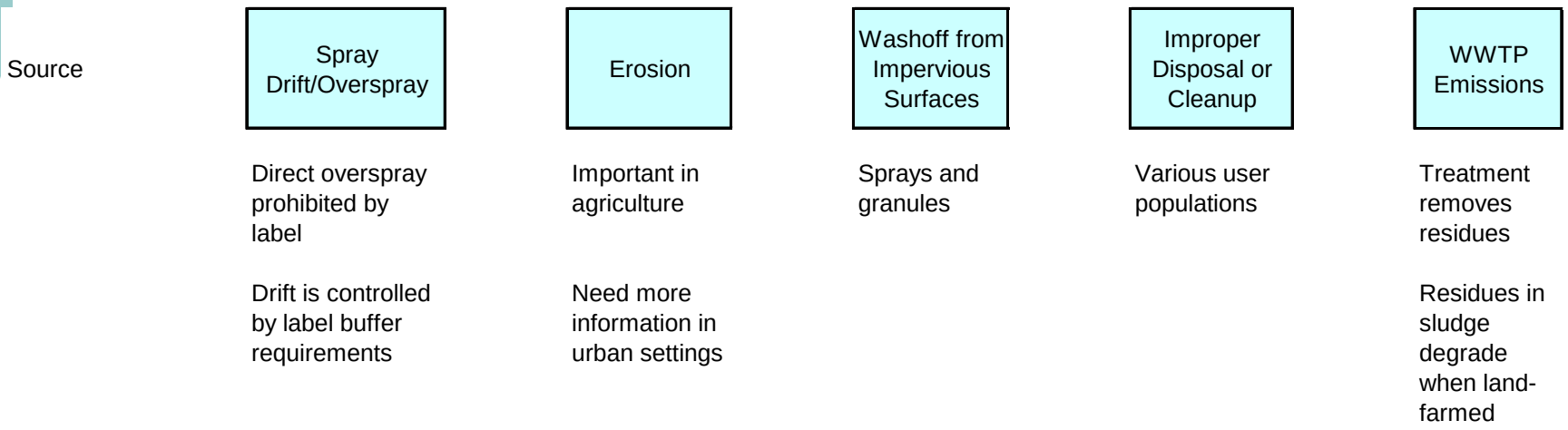
Summary Conceptual Model



Stressor Detailed Model

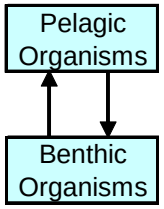


Source Detailed Model



Receptors Detailed Model

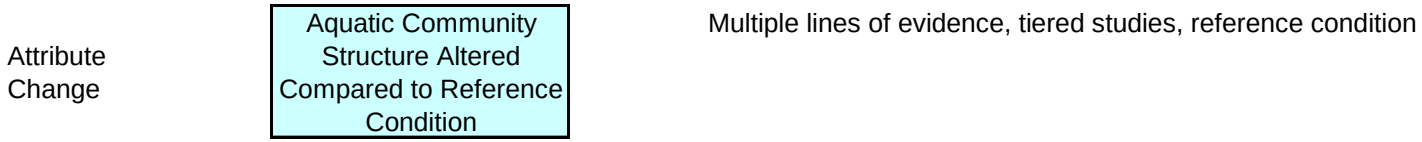
Receptors



Continuum of water body size and habitat, multiple outfalls, mixing zones, bioavailability

Physical habitat stressors, bioavailability

Attribute Change Detailed Model



Analysis Plan - Data

- Data needs by conceptual model category
  - Stressor – usage data for non-crop scenarios
  - Source – types of applications contributing to off-site movement
    - Agriculture use data and practices well understood
    - Greater uncertainty in urban settings and behaviors
    - General: transport occurs on particles
  - Receptors – where do direct effects occur?
    - Focus on bioavailability of residues in sediment
  - Attribute change – benthic community level data
    - Multiple year Central Valley ag. stream monitoring data submitted
    - PWG currently conducting multiple year monitoring of urban streams
    - Defining reference condition would appear to be necessary to determine whether management goal is being met

Analysis Plan - Data

- Data needs specified in CA Notice 2006-13 in relation to problem formulation
  - Existing PWG work products/activities
    - Sediment analytical method developed, validated and submitted
    - Biomonitoring and physical habitat data for urban streams to be supplemented with investigation of sources and transport routes
  - More clarity in how data needs correlate with the management goal and conceptual model would be helpful for the environmental fate and remaining sediment data requirements

Final Analysis Plan

- Key elements
  - How will risk hypothesis be assessed using available and new data?
    - Working hypothesis: multiple pyrethroid residues adversely impact benthic community
  - Delineation of assessment design
  - Data needs
  - Measures
  - Methods
    - e.g., quotients, narrative discussion, stressor-response curve with probabilities
- The PWG looks forward to contributing to the final plan